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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,390

07/24/2003

Robert H. Wham

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UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,390

Applicant(s)

WHAM ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 7, 2007 (phone conversation).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 28-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47 is/are allowed.
- 6) ☒ Claim(s) 1-18, 28-46 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Office action is supplemental to the Final Office action mailed April 13, 2007. It was brought to the examiner's attention that newly filed claims 47 and 48 were not treated in that Office action. Claim 47 would have been subjected only to a double patenting rejection, but applicant's filing of an acceptable Terminal Disclaimer on February 21, 2007 (which TD has just recently been approved) has obviated that issue. Claim 48 is rejected as set forth below. This action restarts the period for response, and remains a Final Office action.

It is noted that the claim for priority is not in accordance with 37 CFR 1.78. The amendment to the specification filed on May 5, 2006 provided a priority claim that failed to indicate the relationship (e.g. Continuation or CIP) of the instant application with the parent applications. See MPEP 201.11(III)(A). It is noted that applicant has timely filed the priority claim in the specification, but has subsequently amended the priority claim in a manner that is not in conformance with the rules.

Also, the Brief Description of the Drawings only makes reference to "Figure 7". The drawings include Figure 7a and Figure 7b. The Brief Description of the Drawings should be amended to provide reference to Figures 7a and 7b.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The oath/declaration acknowledges applicant's duty to disclose information that is material "to the examination" of the application in accordance with 37 CFR 1.56(a). This is improper language, as the oath/declaration should acknowledge the duty to disclose information material "to the patentability" of the application in accordance with 37 CFR 1.56 (not 1.56a).

Claim Rejections - 35 USC § 103

1-13, 16-18, 28-40 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, III (5,836,943) in view of the teaching of Malis et al (5,318,563).

Miller discloses an electrosurgical system and method of treating tissue that comprises a controller for controlling the output pulses of the generator in response to measured tissue characteristics. In particular, Miller specifically teaches that impedance and/or rate of change of impedance is used to control the output of the generator in a method for treating tissue (col. 6, lines 13-61). As disclosed at column 12, lines 64 through column 13, line 10, tissue impedance is measured between pulses, and the generator is then regulated to control subsequent output pulses of the generator. Output pulses are controlled by varying the duty cycle and the magnitude of the output voltage (col. 10, lines 11-20). The Miller reference is silent with regard to the length of the sensing signal (i.e. first pulse). It is noted, however, that Miller clearly teach the use of a low-level measurement pulse that is used to sense complex impedance between pulses of the RF treatment energy (see col. 12, line 64 to col. 13, line 10). The examiner maintains that such a measurement pulse would inherently not

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cause excessive heating of tissue. Moreover, Miller states that the period over which the complex impedance may change may be between 1 millisecond and up to one second (col. 6, lines 40-50). Hence, while Miller alludes to a sensing signal that may be only 1 millisecond, there is no express disclosure of the pulse duration and/or the time between pulses in which the complex impedance is measured.

Malis et al disclose an analogous RF generator system that monitors parameters, such as impedance, to control the output of the generator. In particular, Malis et al teach of known typical values for pulse durations and time between pulses in electrosurgical systems (see col. 8, lines 60 to col. 9, line 8). Specifically, Malis et al disclose microsecond off periods for RF generators. The examiner maintains that the use of similar on/off periods in the Miller system would be well within the purview of the skilled artisan in view of the teaching of Malis et al and would fairly result in the invention as claimed in the rejected claims.

Claims 14, 15, 41, 42 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, III ('943) and Malis et al ('563) and further in view of the teaching of Yates et al (5,558,671).

As addressed above, Miller discloses a system and method for controlling output pulses of a generator for coagulating (i.e. sealing) tissue by monitoring tissue impedance after a pulse (i.e. between pulses) and using the measured impedance to control subsequent pulses. Malis et al discloses typical and/or known pulse periods for

RF generator systems. Miller does not disclose the use of a look-up table as the means to arrive at the values for the subsequent pulses.

Yates et al disclose another tissue sealing device that relies on impedance feedback to control the output of an RF generator. In particular, Yates et al disclose various algorithms for controlling future application of energy based on the sensed impedance including using a look-up table to determine future energy applications (col. 8, lines 8-22). The specific values that may be stored and referenced in such a lookup table are deemed to be obvious to one of ordinary skill in the art.

To have provided the Miller, III system with a look-up table as a means to determine output levels for a generator in response to sensed tissue impedance would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Yates et al.

Response to Arguments

Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.

It is noted that applicant has argued that Miller fails to disclose a pulse having the duration now claimed, or of a pulse that does not excessively heat tissue. With regard to the first point, the examiner agrees that Miller is silent regarding the specific length. However, the examiner maintains that it is generally known in the art that pulse separations may be of lengths well shorter than 200 milliseconds as fairly taught in Malis et al. The examiner further maintains that the Miller measurement signal, which is used solely to measure complex impedance, would not cause excessive heating.

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Finally, the examiner maintains that the since Miller disclose the monitoring of complex impedance and the duration it may last (col. 6, lines 40-50), the information obtained from the measurement period would also correspond to, and fairly indicate, the duration of the complex impedance.

With regard to claims 14 and 41, the examiner maintains that the Yates et al disclosure of the use of a look-up table remains relevant despite not selecting the same parameters. That is, Yates et al teach that a look-up table may be used in lieu of algorithms for determining values in an RF electrosurgical system. That Yates et al is not specifically using the look-up table to arrive at values for the generator is not on point. Miller clearly provides a correlation between measured complex impedance and the output level for voltage and power in subsequent pulses. The correlation is provided by an algorithm in a processor. However, the examiner maintains that Yates et al fairly teach that in lieu of using linear processing to arrive at designated values, look-up tables may be used to provide correlating data to measured signals. One of ordinary skill in the art would certainly recognize that the use of such look-up tables would apply to a wide variety of applications, and the examiner maintains that the skilled artisan would obviously recognize that such a look-up table may be used in place of the Miller algorithms to arrive at pulse characteristics.

Allowable Subject Matter

Claim 47 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner
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mp
June 11, 2007